



## **Alabama Medicaid Preferred Drug and Prior Authorization Program**

### **Prior Authorization (PA) Criteria Instructions**

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This document contains detailed instructions on completing the Medicaid Prior Authorization Form, Form 369. Instructions for completing the Synagis Prior Authorization Form, Form 351, can be found in the Synagis Prior Authorization Instruction Worksheet.

Effective October 1, 2003, as a result of legislation passed in June 2003, the Alabama Medicaid Agency implemented a mandatory Preferred Drug List (PDL). Brand name preferred drugs, generics (unless otherwise specified), and over-the-counter (OTC) drugs for classes reviewed by the Pharmacy and Therapeutics (P&T) Committee and covered by Medicaid are available without prior approval. If, however, a non-preferred drug is prescribed, the practitioner will need to get prior authorization (PA). If approval is given to dispense the non-preferred drug, an authorization number will be given.

Antipsychotic and HIV/AIDS drugs are exempt from the PDL.

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## Section One

### PA Form: General Information

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#### **PDL Drug Classes to Require PA**

The following classes of drugs are on the mandatory preferred drug list.

- [Alzheimer's Agents](#)
- [Antidepressant Agents](#)
- [Antidiabetic Agents](#)
- [Antiemetic Agents](#)
- [Antihistamines \(First Generation\)](#)
- [Antihypertensive Agents](#)
- [Anti-infective Agents](#)
- [Antilipemic Agents](#)
- [Anxiolytics/Sedatives/Hypnotics](#)
- [Cardiac Agents](#)
- [Cerebral Stimulants/Agents used for ADD/ADHD](#)
- [EENT Antiallergic Agents](#)
- [EENT Antibacterial Agents](#)
- [EENT Vasoconstrictor Agents](#)
- [Estrogens](#)
- [Genitourinary Smooth Muscle Relaxants](#)
- [Intranasal Corticosteroids](#)
- [Narcotic Analgesic Agents](#)
- [Platelet-Aggregation Inhibitor Agents](#)
- [Prenatal Vitamins](#)
- [Proton Pump Inhibitors \(PPIs\)](#)
- [Respiratory Agents](#)
- [Selective Serotonin Agonists](#)
- [Skeletal Muscle Relaxants](#)
- [Skin and Mucous Membrane Agents](#)

*Other drug classes may be added as they are reviewed and approved.*

#### **Non-PDL Drugs and/or Drug Classes to Require PA**

The following drugs or classes of drugs are not included on the mandatory preferred drug list and do require PA:

- [Antihistamines \(Second Generation\)](#)
- [Biological Injectables](#)
  - [Amevive<sup>®</sup> \(Alefcept\)](#)
  - [Cimzia<sup>®</sup> \(Certolizumab Pegol\)](#)
  - [Enbrel<sup>®</sup> \(Etanercept\)](#)
  - [Humira<sup>®</sup> \(Adalimumab\)](#)
  - [Kineret<sup>®</sup> \(Anakinra\)](#)
  - [Orencia<sup>®</sup> \(Abatacept\)](#)
  - [Raptiva<sup>®</sup> \(Efalizumab\)](#)
  - [Remicade<sup>®</sup> \(Infliximab\)](#)
  - [Simponi<sup>®</sup> \(Golimumab\)](#)
- [Growth Failure Agents](#)
  - [Adults](#)
  - [AIDS Wasting](#)
  - [Children](#)
- [H2 Antagonists](#)
- [NSAIDs](#)
- [Phosphodiesterase Inhibitors](#)
- [Smoking Cessation](#)
- [Specialized Nutritionals](#)
- [Sustained Release Oral Opioid Agonists](#)
- [Xenical](#)
- [Xolair](#)

## **Definitions**

### **Approval Timeframes**

- The approval timeframe is the maximum period of time for which a PA can be approved. This varies from class to class. Refills within the approved timeframe will not require a new PA request.

### **Appropriate Diagnosis**

- Some classes require diagnosis(es) that justifies the drug requested. Diagnosis(es) **or** ICD-9 code(s) may be used. Use of ICD-9 codes provides specificity and legibility and will usually expedite review.

### **Medical Justification**

- Medical justification is documentation to support the physician's choice for the requested course of treatment and may include documentation from the patient record or peer-reviewed literature. Documentation from the patient record (history and physical, tests, past or current medication/treatments, patient's response to treatment, etc) should illustrate and support the physician's request for the drug specified. For example, if a recommended therapy trial is contraindicated by the patient's condition or the patient has a history of allergy to a first-line drug, and the physician wants to prescribe a non-preferred drug, documentation from the patient record would support that decision. Medical justification may be provided under the Clinical Information Section on the request form or included as an attachment.

### **Prior Treatment Trials**

- Prior authorization requires that a designated number of prescribed generic, OTC or brand name drugs have been utilized unsuccessfully relative to efficacy and/or safety within a specified timeframe prior to requesting the PA. For prior therapy requirements for a specific class, refer to the class specific section of the criteria booklet.
- One prior therapy is acceptable in those instances when a class has only one preferred agent, either brand, generic or OTC, for a specific indication.
- The PA request must indicate that the prescribed generic, OTC or brand drugs have been utilized for a specified period of time **unless** there is an adverse/allergic response or contraindication. See class specific section for the specified number of days of therapy required to meet prior treatment trials.

- If the prescribing practitioner feels there is a medical reason for which the patient should not be on a preferred generic, OTC or brand medication, medical justification may be submitted in lieu of previous drug therapy.
  - The classes below require prior treatment trials. Those classes denoted with an asterisk (\*) require that the failed treatment trials be **prescribed and preferred** agents. Those without an asterisk require that the failed therapies be **prescribed**.
- |  |  |
|--|--|
| • <a href="#"><u>Alzheimer's Agents</u></a> *                | • <a href="#"><u>EENT Vasoconstrictor Agents</u></a> *           |
| • <a href="#"><u>Antidepressant Agents</u></a> *             | • <a href="#"><u>Estrogen Agents</u></a> *                       |
| • <a href="#"><u>Antidiabetic Agents</u></a> *               | • <a href="#"><u>Genitourinary Smooth Muscle Relaxants</u></a> * |
| • <a href="#"><u>Antiemetic Agents</u></a>                   | • <a href="#"><u>H2 Antagonist Agents</u></a>                    |
| • <a href="#"><u>Antihistamines (First Generation)</u></a> * | • <a href="#"><u>Intranasal Corticosteroids Agents</u></a> *     |
| • <a href="#"><u>Antihistamines (Second Generation)</u></a>  | • <a href="#"><u>Narcotic Analgesic Agents</u></a> *             |
| • <a href="#"><u>Antihypertensive Agents</u></a> *           | • <a href="#"><u>NSAID Agents</u></a>                            |
| • <a href="#"><u>Anti-infective Agents</u></a> *             | • <a href="#"><u>Platelet-Aggregation Inhibitor Agents</u></a> * |
| • <a href="#"><u>Antilipemic Agents</u></a> *                | • <a href="#"><u>Prenatal Vitamins</u></a> *                     |
| • <a href="#"><u>Anxiolytics/Sedatives/Hypnotics</u></a> *   | • <a href="#"><u>Proton Pump Inhibitors</u></a> *                |
| • <a href="#"><u>Cardiac Agents</u></a> *                    | • <a href="#"><u>Respiratory Agents</u></a> *                    |
| • <a href="#"><u>Cerebral Stimulants/ADD/ADHD</u></a> *      | • <a href="#"><u>Selective Serotonin Agonists</u></a> *          |
| • <a href="#"><u>EENT Antiallergic Agents</u></a> *          | • <a href="#"><u>Skeletal Muscle Relaxants</u></a> *             |
| • <a href="#"><u>EENT Antibacterial Agents</u></a> *         | • <a href="#"><u>Skin and Mucous Membrane Agents</u></a> *       |

### **Stable Therapy**

- Stable therapy applies in some classes for patients who have been stable on the same drug and the same strength. Stable therapy applies for all classes listed in the chart on the following page. The application of stable therapy for adults is limited to the specific classes listed under the heading "Stable therapy for all ages". Consecutive therapy allows approval for patients who have been determined to be stable on the medication for a specified timeframe and who continue to require therapy. For stable therapy timeframe for a specific class, refer to the class specific section of the criteria booklet.
- Documentation of stable therapy is not required for renewal requests if claims history supports stable therapy. For all other requests, documentation must be provided in order to meet stable therapy requirements. Examples of acceptable documentation include pharmacy profile printouts, prescription copies, copies of the medical record medication list or progress notes documenting strength and quantity consistent with consecutive therapy timeframes. The use of medication samples or manufacturer vouchers does not count towards stable therapy requirements.

The chart on the following page outlines the stable therapy guidelines.

### **Stable Therapy Guideline Chart**

<b>Drug Class</b>	<b>Stable Therapy for All Ages</b>	<b>18 years old and younger</b>
Alzheimer's Agents	√	
Antidepressants	√	
Antidiabetic Agents	√	
Antiemetic Agents		√
Antihistamines (First Generation)		√
Antihistamines (Second Generation)		√
Antihypertensive Agents	√	
Antilipemic Agents		√
Anti-infective Agents	√	
Anxiolytics/Sedatives/Hypnotics		√
Cardiac Agents	√	
Cerebral Stimulants/Agents used for ADD/ADHD	√	
EENT Antiallergic Agents		√
EENT Antibacterial Agents		√
EENT Vasoconstrictor Agents		√
Estrogens		√
Genitourinary Smooth Muscle Relaxants		√
Intranasal Corticosteroids		√
Narcotic Analgesics		√
NSAIDs		√
Platelet-Aggregation Inhibitors	√	
Prenatal Vitamins		√
Prevacid NapraPAC®		√
Proton Pump Inhibitor (PPI) Agents		√
Respiratory Agents		√
Selective Serotonin Agonists		√
Skeletal Muscle Relaxants*	√	
Skin and Mucous Membrane Agents		√
Sustained-release Opioid Agonist (SROA) Agents		√

*\*For Skeletal Muscle Relaxants, stable therapy for adults only applies if patient has a chronic condition associated with spasticity.*

## **Verbal Requests**

PA requests for drugs that meet previous drug usage requirements will be accepted verbally. Verbal PA requests may be initiated by pharmacists, physicians or their authorized representative. Any drug requiring additional information or medical justification must be submitted on the required PA form.

Drugs that may be requested verbally are:

- [Alzheimer's Agents](#)
- [Antidepressants](#)
- [Antidiabetic Agents](#)
- [Antiemetic Agents](#)
- [Antihistamines \(First Generation\)](#)
- [Antihistamines \(Second Generation\)](#)
- [Anti-infective Agents](#)
- [Antilipemic Agents](#)
- [Anxiolytics/Sedatives/Hypnotics](#)
- [Cardiac Agents](#)
- [Cerebral Stimulants/ADD/ADHD](#)
- [EENT Antiallergic Agents](#)
- [EENT Antibacterial Agents](#)
- [EENT Vasoconstrictor Agents](#)
- [Estrogens](#)
- [Genitourinary Smooth Muscle Relaxants](#)
- [H2 Antagonists](#)
- [Intranasal Corticosteroids](#)
- [Narcotic Analgesics](#)
- [NSAIDs](#)
- [Platelet-Aggregation Inhibitors](#)
- [Prenatal Vitamins](#)
- [Proton Pump Inhibitors](#)
- [Respiratory Agents](#)
- [Selective Serotonin Agonists](#)
- [Skeletal Muscle Relaxants](#)
- [Skin and Mucous Membrane Agents](#)

## **Paper Requests**

Page One (1) of the Prior Authorization Request Form may be submitted alone unless the medication requested is listed on Page Two (2). Synagis and Growth Failure Agents have separate PA Forms.

Check the appropriate box at the top of the form to indicate whether one or both pages are being submitted. Acknowledgement of transmission of the second page will ensure that the reviewer has all completed material needed to review the request.

### **Drugs listed on Page 2 of PA form are:**

- Biological Injectables
- Erectile Dysfunction Drugs
- Specialized Nutritionals
- Sustained Release Oral Opioid Agonists
- Xenical
- Xolair

A separate form will need to be completed for each drug/nutritional requested.

Once the form is completed, the paper request can be submitted via fax or mail.

## **Electronic Requests**

Electronic claims are submitted from the pharmacy and electronic requests may be submitted online by the pharmacy or physician.

**Electronic Prior Authorization Program (EPA)** – Certain classes of drugs are included in the EPA Program. Once the pharmacy sends an electronic claim for a drug in the EPA program, the system reviews medical and pharmacy claims history for the patient. If the criteria are met, the claim is automatically assigned an authorization number and is approved. If the PA criteria are not met, a message is returned to the pharmacy instructing the submitter to submit a manual (paper or online) request.

- An EPA rejected claim does not constitute a PA denial, only a notice to the pharmacy that a manual PA request is needed.

Drug classes included in the EPA program:

- [Alzheimer's Agents](#)
- [Antidepressants](#)
- [Antidiabetic Agents](#)
- [Antiemetic Agents](#)
- [Antihistamines \(First Generation\)](#)
- [Antihistamines \(Second Generation\)](#)
- [Antihypertensive Agents](#)
- [Antilipemics](#)
- [Anxiolytics/Sedatives/Hypnotics](#)
- [Cardiac Agents](#)
- [Cerebral Stimulants/ADD/ADHD](#)
- [EENT Antiallergic Agents](#)
- [EENT Vasoconstrictor Agents](#)
- [Estrogens](#)
- [Genitourinary Smooth Muscle Relaxants](#)
- [Intranasal Corticosteroids](#)
- [NSAIDs](#)
- [Platelet-Aggregation Inhibitors](#)
- [Respiratory Agents](#)
- [Selective Serotonin Agonists](#)
- [Skeletal Muscle Relaxants](#)
- [Skin and Mucous Membrane Agents](#)
- [Sustained Release Oral Opioid Agonists](#)

## **Online Form Submission**

From the Medicaid website ([www.alabama.medicaid.gov](http://www.alabama.medicaid.gov)), a link can be found for a PA Request Form that can be completed and submitted electronically online. The form can also be found on HID's (Health Information Designs) website at [www.hidmedicaid.com/terms.html](http://www.hidmedicaid.com/terms.html).

Online requests, once submitted, are processed like paper requests and are subject to paper request requirements.



**Section Two**  
**PA Form: Patient Information**

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Below are fields to be completed on the PA Form.

<b>Form States</b>	<b>Your Response</b>
<b>Patient name</b>	Record the patient's name as it appears on their Medicaid card.
<b>Patient Medicaid #</b>	Record patient's Medicaid number.
<b>Patient DOB</b>	Record patient's date of birth.
<b>Patient phone # with area code</b>	Record the patient's phone number including area code.
<b>Nursing home resident</b>	If patient is nursing home resident, indicate yes.

### Section Three

#### PA Form: Prescriber Information

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Below are fields to be completed on the PA Form.

Form States	Your Response
<b>Prescribing practitioner</b>	Record the prescribing practitioner's name.
<b>NPI/License number</b>	Record the prescribing practitioner's NPI or license number.
<b>Phone number with area code</b>	Record the prescribing practitioner's phone number with area code.
<b>Fax number with area code</b>	Record prescribing practitioner's fax number with area code.
<b>Address (optional)</b>	Prescribing practitioner's mailing address is optional
<b>Prescribing practitioner signature/date</b>	The prescriber should sign and date in this section on the prescribing practitioner signature line.*

*\*By signing in the designated space, the practitioner verifies that the request complies with Medicaid's guidelines and that he/she will be supervising the patient during treatment with the requested product. The practitioner further certifies that documentation is available in the patient record to justify the requested treatment.*

## Section Four PA Form: Clinical Information

*(This information is required for all requests.)*

Below are fields to be completed on the PA Form.

Form States	Your Response
<b>Drug requested</b>	Record the name of the drug being requested.
<b>Strength</b>	Record the strength of the drug.
<b>J Code</b>	Enter the J code if the drug requested is to be administered using office medications.
<b>Quantity</b>	Enter the quantity of the drug being requested.
<b>Days supply</b>	Enter the days supply for the quantity requested.
<b>PA refills</b>	Circle the number of refills requested.
<b>Diagnosis or ICD-9 Code</b>	Record diagnosis(es) that justifies the requested drug. Diagnosis(es) <u>or</u> ICD-9 code(s) may be used. Use of ICD-9 codes provides specificity and legibility and will usually expedite review.
<b>Initial/Renewal Request</b>	Indicate if this is an initial request or a renewal request.
<b>Type of therapy requested</b>	For H2 Antagonists and PPIs, specify if therapy is acute or maintenance.
<b>Medical justification</b>	Explain the reason this drug is required, and attach any additional medical justification necessary.*

*\*Medical justification is documentation to support the physician's choice of the requested course of treatment and may include documentation from the patient record or peer-reviewed literature. Documentation from the patient record (history and physical, tests, past or current medication/treatments, patient's response to treatment, etc) illustrates and supports the physician's request for the drug specified. For example, if a recommended therapy trial is contraindicated by the patient's condition or a history of allergy to a first-line drug, and the physician wants to order a non-preferred drug, documentation from the patient record would support that decision.*

**Section Five**  
**PA Form: Drug Specific Information**

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Below are fields to be completed on the PA Form.

<b>Form States</b>	<b>Your Response</b>
<b>Drug class requested</b>	Check the appropriate box for the drug class for the PA being requested.
<b>Previous drug usage</b>	Record the name of the discontinued medication. If there is no previous drug usage, additional medical justification must be provided.
<b>Reason for d/c</b>	Record the reason the medication was discontinued.
<b>Therapy start date</b>	Record the start date of the discontinued medication.
<b>Therapy end date</b>	Record the end date of the discontinued medication.

## **PA Criteria for Drugs/Drug Classes**

The following section outlines class specific information regarding PA criteria.

### **PDL Drug Classes to Require PA:**

- [Alzheimer's Agents](#)
- [Antidepressant Agents](#)
- [Antidiabetic Agents](#)
- [Antiemetic Agents](#)
- [Antihistamines \(First Generation\)](#)
- [Antihypertensive Agents](#)
- [Anti-infective Agents](#)
- [Antilipemic Agents](#)
- [Anxiolytics/Sedatives/Hypnotics](#)
- [Cardiac Agents](#)
- [Cerebral Stimulants/Agents used for ADD/ADHD](#)
- [EENT Antiallergic Agents](#)
- [EENT Antibacterial Agents](#)
- [EENT Vasoconstrictor Agents](#)
- [Estrogens](#)
- [Genitourinary Smooth Muscle Relaxants](#)
- [Intranasal Corticosteroids](#)
- [Narcotic Analgesic Agents](#)
- [Platelet-Aggregation Inhibitor Agents](#)
- [Prenatal Vitamins](#)
- [Proton Pump Inhibitors \(PPIs\)](#)
- [Respiratory Agents](#)
- [Selective Serotonin Agonists](#)
- [Skeletal Muscle Relaxants](#)
- [Skin and Mucous Membrane Agents](#)

## **Alzheimer's Agents**

### **Appropriate Diagnosis**

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

### **Prior Treatment Trials**

- The patient must also have failed 30-day treatment trials with at least one other prescribed and preferred Alzheimer's agent in this class, either generic, OTC or brand, within the past 6 months, or have a documented allergy or contraindication to all preferred agents in this class.

### **Stable Therapy**

- Stable therapy for this class is defined as a 90-day or greater timeframe. Approval may be given for those who have documented stable therapy on the requested medication for 90 consecutive days or greater.

### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 12 months.

### **Electronic Prior Authorization (PA)**

- Alzheimer's agents are included in the electronic PA program.

### **Verbal PA Requests**

- PA requests that meet prior usage requirement for approval may be accepted verbally.

## **Antidepressants**

### **Appropriate Diagnosis**

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

### **Prior Treatment Trials**

- The patient must also have failed 30-day treatment trials with at least two prescribed and preferred antidepressant agents in this class, either generic, OTC or brand within the past 6 months, or have a documented allergy or contraindication to all preferred agents in this class.

### **Stable Therapy**

- Approval may be given to those who have documented stable therapy on the requested medication for 60 consecutive days or greater.

### **Medical Justification**

- Medical justification may include peer reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 12 months.

### **Electronic Prior Authorization (PA)**

- Antidepressants are included in the electronic PA program.

### **Verbal PA Requests**

- PA requests that meet prior usage requirement for approval may be accepted verbally.

## **Antidiabetic Agents**

### **Appropriate Diagnosis**

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

### **Prior Treatment Trials**

- The patient must also have failed 30-day treatment trials with at least two prescribed and preferred antidiabetic agents, either generic, OTC or brand, within the past 6 months, or have a documented allergy or contraindication to all preferred agents in this class.
- If the request is for Avandia<sup>®</sup>, Avandamet<sup>®</sup>, or Avandaryl<sup>®</sup>, the patient must also have failed a 30-day treatment trial with at least two prescribed and preferred antidiabetic agents (of which one is Actos<sup>®</sup>), either generic, OTC or brand, within the past 6 months
- If the request is for Symlin<sup>®</sup>, the patient must also be on insulin therapy and have a hemoglobin A1c greater than 7% despite more than 90 days of insulin therapy.

### **Stable Therapy**

- Approval may be given for those who have documented stable therapy on the requested medication for 60 consecutive days or greater.

### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 12 months.

### **Electronic Prior Authorization (PA)**

- Antidiabetic agents, excluding Symlin<sup>®</sup>, are included in the electronic PA program.

### **Verbal PA Requests**

- PA requests that meet prior usage requirement for approval may be accepted verbally.



## **Antiemetic Agents**

### **Appropriate Diagnosis**

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

### **Prior Treatment Trials**

- The patient must also have failed 3-day treatment trials with at least two prescribed antiemetics, to include promethazine or a preferred antiemetic agent, either generic, OTC or brand, within the past 6 months, or have a documented allergy or contraindication to all preferred agents in this class.

### **Stable Therapy**

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 12 months.

### **Electronic Prior Authorization (PA)**

- Antiemetic agents are included in the electronic PA program.
- Through the Electronic PA program, allowances are made for patients with a cancer diagnosis to receive Emend<sup>®</sup> and for patients with a HIV/AIDs diagnosis to receive Marinol<sup>®</sup> (supported by medical claims history).

### **Verbal PA Requests**

- PA requests that meet prior usage requirement for approval may be accepted verbally.

## **Antihistamines (First Generation)**

### **Appropriate Diagnosis**

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

### **Prior Treatment Trials**

- The patient must also have failed 30-day treatment trials with at least two prescribed and preferred agents in this class, either generic, OTC or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

### **Stable Therapy**

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 12 months.

### **Electronic Prior Authorization (PA)**

- Antihistamines are included in the electronic PA program.

### **Verbal PA Requests**

- PA requests that meet prior usage requirement for approval may be accepted verbally.

## **Antihypertensive Agents**

### **Appropriate Diagnosis**

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

### **Prior Treatment Trials**

- The patient must also have failed 30-day treatment trials with at least two prescribed and preferred antihypertensive agents in this class, either generic, OTC or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.
- To meet these prior usage requirements, drugs within this specific classification must be judged against others in the same class (AHFS specific). For example, to qualify for a non-preferred beta-blocker, the patient must have met prior usage requirements of 30-day treatment trials with two other preferred beta-blockers, either generic, OTC or brand.
- For fixed-dose combination products containing drugs from 2 different subclasses, prior therapies must include at least 2 prescribed and preferred agents from either or both respective subclasses.
- For BiDil<sup>®</sup>, in lieu of prior usage requirements, approval may be obtained for adjunctive therapy to standard heart failure therapy (including a diuretic, angiotensin converting enzyme inhibitor or angiotensin II receptor antagonist, and beta-blocker) in self-identified black patients.
- For Samsca<sup>®</sup>, patients must have a documented serum sodium <125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction. Patients must also have documentation of being initiated on Samsca<sup>®</sup> in an inpatient setting.
- For Tekturna<sup>®</sup>, prior therapies must include at least two prescribed and preferred angiotensin-converting enzyme inhibitors and/or angiotensin II receptor antagonists.

### **Stable Therapy**

- Approval may be given for those who have documented stable therapy on the requested medication for 60 consecutive days or greater.

### **Medical Justification**

- Medical justification may include peer reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 12 months.

### **Electronic Prior Authorization (PA)**

- Antihypertensive agents are included in the electronic PA program.

### **Verbal PA Requests**

- Not Applicable

## **Anti-infective Agents**

### **Appropriate Diagnosis**

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

### **Prior Treatment Trials**

- The patient must also have failed two treatment trials of no less than three-days each, with at least two prescribed and preferred anti-infectives, either generic, OTC or brand, for the above diagnosis within the past 30 days or have a documented allergy or contraindication to all preferred agents for the diagnosis submitted.

### **Stable Therapy**

- Patients on anti-infective therapy while institutionalized once discharged or transferred to another setting or patients having a 60 day consecutive stable therapy may continue on that therapy with supportive medical justification or documentation.

### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested. Approval may also be given, with medical justification, if the medication requested is indicated for first line therapy when there are no other indicated preferred agents available or if indicated by susceptibility testing or evidence of resistance to all preferred agents.

### **PA Approval Timeframes**

- Approval may be given for up to 12 months.

### **Electronic Prior Authorization (PA)**

- Not Applicable

### **Verbal PA Requests**

- PA requests that meet prior usage requirement for approval may be accepted verbally.

## **Antilipemic Agents**

### **Appropriate Diagnosis**

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

### **Prior Treatment Trials**

- The patient must also have failed 30-day treatment trials with at least two prescribed and preferred lipid lowering agents, either generic, OTC or brand, within the past 6 months, or have a documented allergy or contraindication to all preferred agents in this class.
- For Zetia<sup>®</sup>, if prior usage requirements have not been met, approval may be obtained for adjunctive therapy to a current lipid lowering drug.

### **Stable Therapy**

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

### **Medical Justification**

- Medical justification may include peer reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 6 months for initial request and up to 12 months for renewal requests.

### **Electronic Prior Authorization (PA)**

- Antilipemic agents are included in the electronic PA program.

### **Verbal PA Requests**

- PA requests that meet prior usage requirement for approval may be accepted verbally.

## **Anxiolytics/Sedatives/Hypnotics**

### **Appropriate Diagnosis**

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

### **Prior Treatment Trials**

- The patient must also have failed 30-day treatment trials with at least two prescribed and preferred agents in this class, either generic, OTC or brand within the past 6 months, or have a documented allergy or contraindication to all preferred agents in this class.

### **Stable Therapy**

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 3 months for initial request and up to 6 months for renewal requests.

### **Electronic Prior Authorization (PA)**

- Anxiolytic, sedative and hypnotic agents are included in the electronic PA program.

### **Verbal PA Requests**

- PA requests that meet prior usage requirement for approval may be accepted verbally.

## **Cardiac Agents**

### **Appropriate Diagnosis**

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

### **Prior Treatment Trials**

- The patient must also have failed 30-day treatment trials with at least two prescribed and preferred cardiac agents in this class, either generic, OTC or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.
- To meet these prior usage requirements, drugs within this specific classification must be judged against others in the same class (AHFS specific).
  - For example, to qualify for a non-preferred cardiotonic, the patient must have met prior usage requirements of 30-day treatment trials with two other preferred cardiotonic agents, either generic, OTC or brand.
  - For Ranexa<sup>®</sup>, in lieu of prior usage requirements, approval may be obtained for adjunctive therapy to a current antianginal drug.

### **Stable Therapy**

- Approval may be given for those who have documented stable therapy on the requested medication for 60 consecutive days or greater.

### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 12 months.

### **Electronic Prior Authorization (PA)**

- Cardiac agents are included in the electronic PA program.

### **Verbal PA Requests**

- PA requests that meet prior usage requirement for approval may be accepted verbally.

## **Cerebral Stimulants/Agents Used for ADD/ADHD**

### **Appropriate Diagnosis**

- The patient must have an appropriate diagnosis supported by documentation in the patient record.
- For agents with an FDA-approved indication of Idiopathic hypersomnia in children 18 and under, narcolepsy, or obstructive sleep apnea, the patient must have an appropriate diagnosis supported by documentation in the patient record of appropriate diagnostic testing.

### **Prior Therapy**

- If the request is for a *short- or intermediate-acting* cerebral stimulant/agent used to treat ADD/ADHD, the patient must also have failed 30-day treatment trials with at least two prescribed and preferred short- or intermediate-acting cerebral stimulants/agents used for ADD/ADHD, either generic, OTC or brand, within the past 6 months.
- If the request is for a *long-acting* cerebral stimulant/agent used for ADD/ADHD, the patient must also have failed 30-day treatment trials with at least two prescribed and preferred long-acting cerebral stimulants/agents used for ADD/ADHD, either generic, OTC or brand within the past 6 months.
- If the request is for Strattera<sup>®</sup>, the patient must also have failed 30-day treatment trials with at least two prescribed and preferred cerebral stimulants (short-, intermediate- or long-acting), either generic, OTC or brand within the past 6 months. If prior usage requirements have not been met, approval may be given if there is a history of substance abuse or concern regarding substance abuse in the patient's household.
- If the request is for Intuniv<sup>®</sup>, the patient must also have failed a 30-day treatment trial with immediate-release guanfacine within the past 6 months. In addition, the patient must also have failed 30-day treatment trials with at least two prescribed and preferred cerebral stimulants (short-, intermediate- or long-acting), either generic, OTC or brand within the past 6 months. If prior usage requirements have not been met, approval may be given if there is a history of substance abuse or concern regarding substance abuse in the patient's household.
- In lieu of prior usage requirements, approval may be given if there is a documented allergy or contraindication to all preferred agents in this class.

### **Stable Therapy**

- Approval may be given to those who have documented stable therapy on the requested medication for 60 consecutive days or greater.

### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.



**PA Approval Timeframes**

- Approval may be given for up to 12 months.

**Electronic Prior Authorization (PA)**

- Cerebral Stimulant/Agent Used for ADD/ADHD agents are included in the electronic PA program.

**Verbal PA Requests**

- PA requests that meet prior usage requirement for approval may be accepted verbally.

## **EENT Antiallergic Agents**

### **Appropriate Diagnosis**

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

### **Prior Treatment Trials**

- For ophthalmic products, the patient must also have failed 14-day treatment trials with at least two prescribed and preferred ophthalmic agents in this class, either generic, OTC or brand, within the past 12 months or have a documented allergy or contraindication to all preferred agents in this class.
- For nasal products, the patient must have also failed 14-day treatment trials with at least two prescribed antiallergic agents, to include oral antihistamines, intranasal corticosteroids or intranasal cromolyn, either generic, OTC or brand within the past 12 months or have a documented allergy or contraindication to all preferred or acceptable agents.

### **Stable Therapy**

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

### **Medical Justification**

- Medical justification may include peer reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 12 months.

### **Electronic Prior Authorization (PA)**

- EENT antiallergic agents are included in the electronic PA program.

### **Verbal PA Requests**

- PA requests that meet prior usage requirement for approval may be accepted verbally.

## **EENT Antibacterial Agents**

### **Appropriate Diagnosis**

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

### **Prior Treatment Trials**

- The patient must also have failed 3-day treatment trials with at least two prescribed and preferred agents in this class, either generic, OTC or brand, within the past 30 days or have a documented allergy or contraindication to all preferred agents in this class.

### **Stable Therapy**

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 12 months.

### **Electronic Prior Authorization (PA)**

- EENT antibacterials are not included in the electronic PA program.

### **Verbal PA Requests**

- PA requests that meet prior usage requirement for approval may be accepted verbally.

## **EENT Vasoconstrictor Agents**

### **Appropriate Diagnosis**

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

### **Prior Treatment Trials**

- The patient must also have failed 3-day treatment trials with at least two prescribed and preferred agents in this class, either generic, OTC or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

### **Stable Therapy**

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 12 months.

### **Electronic Prior Authorization (PA)**

- EENT vasoconstrictors are included in the electronic PA program.

### **Verbal PA Requests**

- PA requests that meet prior usage requirement for approval may be accepted verbally.

## **Estrogens**

### **Appropriate Diagnosis**

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

### **Prior Treatment Trials**

- The patient must also have failed 30-day treatment trials with at least two prescribed and preferred estrogens in this class, either generic, OTC or brand, within the past 6 months, or have a documented allergy or contraindication to all preferred agents in this class.

### **Stable Therapy**

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

### **Medical Justification**

- Medical justification may include peer reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 12 months.

### **Electronic Prior Authorization (PA)**

- Estrogens are included in the electronic PA program.

### **Verbal PA Requests**

- PA requests that meet prior usage requirement for approval may be accepted verbally.

## **Genitourinary Smooth Muscle Relaxants**

### **Appropriate Diagnosis**

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

### **Prior Treatment Trials**

- The patient must also have failed 30-day treatment trials with at least two prescribed and preferred agents in this class, either generic, OTC or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

### **Stable Therapy**

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 12 months.

### **Electronic Prior Authorization (PA)**

- Genitourinary smooth muscle relaxants are included in the electronic PA program.

### **Verbal PA Requests**

- PA requests that meet prior usage requirement for approval may be accepted verbally.

## **Intranasal Corticosteroids**

### **Appropriate Diagnosis**

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

### **Prior Treatment Trials**

- The patient must also have failed 30-day treatment trials with at least two prescribed and preferred intranasal corticosteroids in this class, either generic, OTC or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

### **Stable Therapy**

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 12 months.

### **Electronic Prior Authorization (PA)**

- Intranasal corticosteroid agents are included in the electronic PA program.

### **Verbal PA Requests**

- PA requests that meet prior usage requirement for approval may be accepted verbally.

## **Narcotic Analgesics**

### **Appropriate Diagnosis**

- The patient must have an appropriate diagnosis supported by documentation in the patient record.
- For Subutex® and/or Suboxone®, the patient must have the diagnosis of opioid type dependence and the physician must have received a waiver and special DEA number through the Center for Substance Abuse Treatment (CSAT) to practice medication-assisted opioid addiction therapy.

### **Prior Treatment Trials**

- The patient must also have failed 30-day treatment trials with at least 2 prescribed and preferred narcotic analgesics in this class, either generic, OTC, or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

### **Stable Therapy**

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

### **Medical Justification**

- For narcotic analgesics, medical justification must include documentation of therapeutic pain management failure with NSAIDs, APAP, or ASA and a complete pain evaluation in the medical record. Type of pain (acute versus chronic) and pain intensity (mild, moderate or severe) must be indicated in the Drug/Clinical Information section under Medical Justification. Medical justification may also include peer-reviewed literature, medical record documentation or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 3 months with initial and renewal requests unless one of the qualifying diagnoses is indicated, then approval may be given for up to 6 months. If the patient is a nursing home resident, approval may be given for up to 6 months for initial requests and up to 12 months for renewal requests.

### **Electronic Prior Authorization (PA)**

- Not Applicable

### **Verbal PA Requests**

- PA requests that meet prior usage requirement for approval may be accepted verbally.



## **Platelet-Aggregation Inhibitors**

### **Appropriate Diagnosis**

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

### **Prior Treatment Trials**

- The patient must also have failed 30-day treatment trials with at least 2 prescribed and preferred platelet-aggregation inhibitors in this class, either generic, OTC, or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

### **Stable Therapy**

- Approval may be given to those who have documented stable therapy on the requested medication for 60 consecutive days or greater.

### **Medical Justification**

- Acceptable medical justification consists of specific clinical diagnoses for 1<sup>st</sup> line treatment by certain branded products in lieu of prior usage, allergy, contraindication or intolerance to the use of aspirin, cilostazol, ticlopidine and dipyridamole.
- Clinical literature and guidelines support the use of Aggrenox<sup>®</sup>, Effient<sup>®</sup> and Plavix<sup>®</sup> for specific 1<sup>st</sup> line indications; these indications include acute coronary syndrome, acute myocardial infarction (NSTEMI and STEMI), peripheral arterial occlusive disease (PAD, PVD), transient ischemia or ischemic stroke due to thrombosis/embolism, and percutaneous coronary interventions (balloon angioplasty, laser angioplasty, intra-coronary stents, other catheter devices treating coronary atherosclerosis).

### **PA Approval Timeframes**

- Approval may be given for up to 12 months.

### **Electronic Prior Authorization (PA)**

- Platelet-aggregation inhibitors are included in the electronic PA program.

### **Verbal PA Requests**

- PA requests that meet prior usage requirement for approval may be accepted verbally.

## **Prenatal Vitamins**

### **Appropriate Diagnosis**

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

### **Prior Treatment Trials**

- The patient must also have failed 30-day treatment trials with at least two prescribed and preferred agents in this class, either generic, OTC or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

### **Stable Therapy**

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 12 months.

### **Electronic Prior Authorization (PA)**

- Prenatal vitamins are not included in the electronic PA program.

### **Verbal PA Requests**

- PA requests that meet prior usage requirement for approval may be accepted verbally.

## **Proton Pump Inhibitors** **(PPI)**

### **Appropriate Diagnosis**

- The patient must have an appropriate diagnosis supported by documentation in the patient record. Requests must indicate under the Clinical Information Section of the PA Request Form whether medication is for acute or maintenance therapy.

### **Prior Treatment Trials**

- The patient must also have failed 30-day treatment trials with at least 2 prescribed and preferred PPIs in this class, either generic, OTC, or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

### **Stable Therapy**

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

### **Medical Justification**

- Medical justification for consideration for approval outside criteria is diagnosis driven and outlined as follows:

#### **GERD**

##### ➤ **Mild to moderate GERD (Grade I, II, or III)**

Medical justification documentation must indicate failure of preferred agents in this class prescribed for at least 8 weeks with persistence of symptoms.

Testing is not required for acute therapy with moderate to severe symptoms, defined as  $\geq 2$  episodes/week of nocturnal heartburn, and  $\geq 3$  episodes/week of daytime heartburn or indigestion, with no resolution or worsening of symptoms.

Approval may be given for up to 4 weeks of **acute** therapy.

If moderate to severe symptoms persist and there is documentation in the medical record, an additional 8 weeks of treatment may be approved without testing. If symptoms persist, documentation of appropriate testing (barium contrast or double contrast radiography, or endoscopy) with results is required for approval of additional **maintenance** therapy.

##### ➤ **Severe GERD (Grade IV or V)**

Diagnosis must be confirmed by testing (barium contrast or double contrast radiography, or endoscopy) within the past 12 months.

For **acute** therapy, the patient may be approved for up to 8 weeks of therapy. If severe GERD symptoms continue or do not resolve, approval for **maintenance** therapy may be given for an additional 12 weeks of treatment.

### **Positive H. pylori**

If the patient has tested positive for H. pylori (breath test, blood test or tissue biopsy if endoscopic exam done) and met prior usage requirements, approval may be given for up to 2 weeks of combination therapy.

Requests for Prevpac® should meet Prevpac® criteria, not PPI criteria.

### **Gastric ulcer, duodenal ulcer, or esophagitis**

The patient must have an appropriate diagnosis confirmed by testing (barium contrast or double contrast radiography, or endoscopy) within the past 12 months and meet prior usage requirements. If these requirements are met, up to 8 weeks of **acute** therapy may be approved.

If on completion of 8 weeks of acute treatment for esophagitis (erosive or non-erosive) symptoms persist, approval may be given for up to 6 months of maintenance treatment.

After 12 months, approval will require documentation of persistent symptoms and the results of retesting.

### **Hypersecretory conditions**

If the patient is diagnosed with Barrett's Esophagitis, Zollinger-Ellison, or other hypersecretory disorders, which have been confirmed by testing (barium contrast or double contrast radiography, or endoscopy), then approval of up to 12 months of **acute** treatment may be issued, with continued **maintenance** therapy approved in 12 month increments.

Renewal requests do not require retesting but do need documentation of persistence of symptoms.

### **PrevPac®**

The patient must have a diagnosis of duodenal ulcer, confirmed by testing within the past 12 months, and must also test positive for H. pylori, confirmed by testing within the past 30 days.

The patient must have failed two acute treatment trials of at least 14 days each with lack of healing on an acid suppressor and 2 antibiotics, either generic, OTC or brand, within the past 6 months or have a documented contraindication to all preferred agents in these classes.

### **PA Timeframe Approval**

- Approval may be given for up to 12 months for maintenance. Otherwise, please see above.

### **Electronic Prior Authorization**

- Not applicable

**Verbal PA Requests**

- PA requests that meet prior usage requirements for approval may be accepted verbally.

## **Respiratory Agents**

### **Appropriate Diagnosis**

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

### **Prior Treatment Trials**

- For a diagnosis of allergic rhinitis, the patient must also have failed 30-day treatment trials with at least two prescribed intranasal agents or oral agents (to include second generation antihistamines) to treat allergic rhinitis, either generic, OTC or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.
- For all other diagnoses, the patient must also have failed 30-day treatment trials with at least two prescribed and preferred respiratory agents in this class, either generic, OTC or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.
- Requests for Pulmicort Respules<sup>®</sup> or Singulair<sup>®</sup> will not require failed therapy for children under age five with a diagnosis of asthma.

### **Stable Therapy**

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 12 months.

### **Electronic Prior Authorization (PA)**

- Respiratory agents are included in the electronic PA program.

### **Verbal PA Requests**

- PA requests that meet prior usage requirement for approval may be accepted verbally.

## **Selective Serotonin Agonists**

### **Appropriate Diagnosis**

- The patient must have an appropriate diagnosis supported by documentation in the patient record.
- The request must be for acute treatment, not prophylactic therapy.

### **Prior Treatment Trials**

- The patient must have failed 2-week treatment trials with at least two other prescribed and preferred selective serotonin agonists, either generic, OTC or brand, within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.

### **Stable Therapy**

- Approval may be given for children age 18 years and under who have been stable on the requested medication for 60 consecutive days or greater.

### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 6 months initially and up to 12 months for renewal requests.

### **Electronic Prior Authorization (PA)**

- Selective serotonin agonists are included in the electronic PA program.

### **Verbal PA Requests**

- PA requests that meet prior usage requirement for approval may be accepted verbally.

## **Skeletal Muscle Relaxants**

### **Appropriate Diagnosis**

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

### **Prior Treatment Trials**

- The patient must have also failed 30-day treatment trials with at least two prescribed and preferred skeletal muscle relaxants, either generic, OTC or brand, within the past six (6) months or have a documented allergy or contraindication to all preferred agents in this class.

### **Stable Therapy**

- Approval may be given if the patient has been on consecutive 60 day or greater treatment if the skeletal muscle relaxant being requested is for a chronic condition associated with muscle spasticity.
- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 6 months initially and up to 12 months for renewal requests for chronic conditions with muscle spasticity.
- For acute conditions approval may be granted for up to a 10-day course of medication consistent with current maximum limits when criteria are met.

### **Electronic Prior Authorization (PA)**

- Skeletal muscle relaxant agents are included in the electronic PA program.

### **Verbal PA Requests**

- PA requests that meet prior usage requirement for approval may be accepted verbally



## **Skin and Mucous Membrane Agents**

### **Appropriate Diagnosis**

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

### **Prior Treatment Trial**

- The patient must also have failed 30-day treatment trials with at least two prescribed and preferred skin and mucous membrane agents in this class, either generic, OTC or brand, within the past 6 months, or one failed treatment trial when appropriate based on PDL preferred agents, or have a documented allergy or contraindication to all preferred agents in this class.
- For scabicides and pediculicides, the patient must have failed 14-day treatment trials with at least two prescribed and preferred skin and mucous membrane agents in this class, either generic, OTC or brand within the past 6 months or have a documented allergy or contraindication to all preferred agents in this class.
- To meet prior usage requirements, drugs within this specific classification must be judged against others in the same class (AHFS specific).
  - For example, to qualify for a non-preferred topical anti-inflammatory agent, the patient must have met prior usage requirements of 30-day treatment trials with two other topical anti-inflammatory agents, either generic or brand.

### **Stable Therapy**

- Approval may be given for children age 18 years and under who have been stable on the requested medication for 60 consecutive days or greater.

### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 12 months.

### **Electronic Prior Authorization (PA)**

- Skin and mucous membrane agents are included in the electronic PA program.

### **Verbal PA Requests**

- PA requests that meet prior usage requirement for approval may be accepted verbally.

## **Non-PDL Drugs and/or Drug Classes to Require PA**

- [Antihistamines \(Second Generation\)](#)
- [Biological Injectables](#)
  - [Amevive<sup>®</sup> \(Alefaccept\)](#)
  - [Cimzia<sup>®</sup> \(Certolizumab Pegol\)](#)
  - [Enbrel<sup>®</sup> \(Etanercept\)](#)
  - [Humira<sup>®</sup> \(Adalimumab\)](#)
  - [Kineret<sup>®</sup> \(Anakinra\)](#)
  - [Orencia<sup>®</sup> \(Abatacept\)](#)
  - [Raptiva<sup>®</sup> \(Efalizumab\)](#)
  - [Remicade<sup>®</sup> \(Infliximab\)](#)
  - [Simponi<sup>®</sup> \(Golimumab\)](#)
- [Growth Failure Agents](#)
  - [Adults](#)
  - [AIDS Wasting](#)
  - [Children](#)
- [H2 Antagonists](#)
- [NSAIDs](#)
- [Phosphodiesterase Inhibitors](#)
- [Smoking Cessation](#)
- [Specialized Nutritionals](#)
- [Sustained Release Oral Opioid Agonists](#)
- [Xenical](#)
- [Xolair](#)

## **Antihistamines (Second Generation)**

### **Appropriate Diagnosis**

- The patient must have an appropriate diagnosis supported by documentation in the patient record.

### **Prior Treatment Trials**

- The patient must also have failed 30-day treatment trials with at least two prescribed antihistamines, either generic, OTC or brand within the past 6 months, or have a documented allergy or contraindication to all covered OTC or generic antihistamine agents.

### **Stable Therapy**

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 12 months.

### **Electronic Prior Authorization (PA)**

- Second generation antihistamines are included in the electronic PA program.

### **Verbal PA Requests**

- PA requests that meet prior usage requirement for approval may be accepted verbally.

## **Biological Injectables**

### **Check the applicable drug:**

- Amevive<sup>®</sup> (Alefcept)
- Cimzia<sup>®</sup> (Certolizumab Pegol)
- Enbrel<sup>®</sup> (Etanercept)
- Humira<sup>®</sup> (Adalimumab)
- Kineret<sup>®</sup> (Anakinra)
- Orencia<sup>®</sup> (Abatacept)
- Raptiva<sup>®</sup> (Efalizumab)
- Remicade<sup>®</sup> (Infliximab)
- Simponi<sup>®</sup> (Golimumab)

### **A. Amevive<sup>®</sup> (Alefcept)**

#### **Appropriate Diagnosis**

- For prior authorization the patient must have a diagnosis of:
  - chronic moderate to severe plaque psoriasis in adults 18 years or older confirmed by a board certified dermatologist.

#### **Prior Treatment Trials**

- The patient must have had an inadequate response to phototherapy, systemic retinoids, methotrexate or cyclosporine, or failed a 6-month treatment trial with topical treatment(s), either generic, OTC, or brand, within the last year, or have a documented allergy or contraindication to all agents in this class.

#### **Stable Therapy**

- Stable therapy does not apply to Amevive<sup>®</sup>.

#### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

#### **PA Approval Timeframes**

- Renewal requests can only be approved provided the CD4+ T lymphocyte counts are within normal range and a minimum of a 12-week interval has passed since the previous course of treatment.

#### **Electronic Prior Authorization (PA)**

- Not Applicable

#### **Verbal PA Requests**

- Not Applicable

## **B. Cimzia® (Certolizumab Pegol)**

### **Appropriate Diagnosis**

- For prior authorization the patient must have a diagnosis of:
  - moderately to severely active rheumatoid arthritis in adults 18 years or older confirmed by a board certified rheumatologist, or
  - moderately to severely active Crohn's disease in adults 18 years or older confirmed by a board certified gastroenterologist.

### **Prior Treatment Trials**

- For rheumatoid arthritis, the patient must also have failed a 30-day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use. DMARDs include the following: hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, d-penicillamine, azathioprine, oral gold, intramuscular gold.
- For Crohn's disease, the patient must have had an inadequate response to one or more conventional therapies, which include aminosaliclates, corticosteroids, azathioprine/6-mercaptopurine, metronidazole, methotrexate, or ciprofloxacin.

### **Stable Therapy**

- Stable therapy does not apply to Cimzia®.

### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 12 months.

### **Electronic Prior Authorization (PA)**

- Not Applicable

### **Verbal PA Requests**

- Not Applicable

## **C. Enbrel® (Etanercept)**

### **Appropriate Diagnosis**

- For prior authorization the patient must have a diagnosis of:
  - moderately to severely active rheumatoid arthritis, moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years or older, or active ankylosing spondylitis confirmed by a board certified rheumatologist, or
  - psoriatic arthritis confirmed by a board certified dermatologist or rheumatologist, or
  - moderate to severe plaque psoriasis in adults 18 years or older confirmed by a board certified dermatologist.

### **Prior Treatment Trials**

- For ankylosing spondylitis, the patient must also have failed a 3-month treatment trial with at least two nonsteroidal anti-inflammatory agents (NSAIDs) at maximum recommended doses, unless there is a documented adverse response or contraindication to NSAID use. Patients who have axial disease only do not require any additional treatment failures. Patients with symptoms of peripheral arthritis must also have failed a 30-day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use. DMARDs include the following: hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, d-penicillamine, azathioprine, oral gold, intramuscular gold.
- For juvenile idiopathic arthritis or psoriatic arthritis, the patient must also have failed a 30-day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use. DMARDs include the following: hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, d-penicillamine, azathioprine, oral gold, intramuscular gold.
  - For rheumatoid arthritis that is newly diagnosed with high disease activity for <3 months with features of poor prognosis, therapy can be initiated with methotrexate and Enbrel®.
- For plaque psoriasis, the patient must have had an inadequate response to phototherapy, systemic retinoids, methotrexate or cyclosporine, or failed a 6-month treatment trial with topical treatment(s), either generic, OTC, or brand, within the last year, or have a documented allergy or contraindication to all agents in this class.

### **Stable Therapy**

- Stable therapy does not apply to Enbrel®.

### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

**PA Approval Timeframes**

- Approval may be given for up to 12 months.

**Electronic Prior Authorization (PA)**

- Not Applicable

**Verbal PA Requests**

- Not Applicable

## **D. Humira® (Adalimumab)**

### **Appropriate Diagnosis**

- For prior authorization the patient must have a diagnosis of:
  - moderately to severely active rheumatoid arthritis or active ankylosing spondylitis in adults 18 years or older confirmed by a board certified rheumatologist, or
  - moderately to severely active polyarticular juvenile idiopathic arthritis in patients 4 to 17 years of age confirmed by a board certified rheumatologist, or
  - psoriatic arthritis in adults 18 years or older confirmed by a board certified rheumatologist or dermatologist, or
  - moderately to severely active Crohn's disease in adults 18 years or older confirmed by a board certified gastroenterologist, or
  - moderate to severe chronic plaque psoriasis in adults 18 years or older confirmed by a board certified dermatologist.

### **Prior Treatment Trials**

- For ankylosing spondylitis, the patient must also have failed a 3-month treatment trial with at least two nonsteroidal anti-inflammatory agents (NSAIDs) at maximum recommended doses, unless there is a documented adverse response or contraindication to NSAID use. Patients who have axial disease only do not require any additional treatment failures. Patients with symptoms of peripheral arthritis must also have failed a 30-day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use. DMARDs include the following: hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, d-penicillamine, azathioprine, oral gold, intramuscular gold.
- For rheumatoid arthritis, juvenile idiopathic arthritis or psoriatic arthritis, the patient must also have failed a 30-day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use. DMARDs include the following: hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, d-penicillamine, azathioprine, oral gold, intramuscular gold.
  - For rheumatoid arthritis that is newly diagnosed with high disease activity for <3 months with features of poor prognosis, therapy can be initiated with methotrexate and Humira®.
- For Crohn's disease, the patient must have had an inadequate response to one or more conventional therapies, which include aminosalicylates, corticosteroids, azathioprine/6-mercaptopurine, metronidazole, methotrexate, or ciprofloxacin.



- For plaque psoriasis, the patient must have had an inadequate response to phototherapy, systemic retinoids, methotrexate or cyclosporine, or failed a 6-month treatment trial with topical treatment(s), either generic, OTC, or brand, within the last year, or have a documented allergy or contraindication to all agents in this class.

**Stable Therapy**

- Stable therapy does not apply to Humira®.

**Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

**PA Approval Timeframes**

- Approval may be given for up to 12 months.

**Electronic Prior Authorization (PA)**

- Not Applicable

**Verbal PA Requests**

- Not Applicable

## **E. Kineret<sup>®</sup> (Anakinra)**

### **Appropriate Diagnosis**

- For prior authorization the patient must have a diagnosis of:
  - moderately to severely active rheumatoid arthritis in adults 18 years or older confirmed by a board certified rheumatologist.

### **Prior Treatment Trials**

- The patient must also have failed a 30-day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use. DMARDs include the following: hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, d-penicillamine, azathioprine, oral gold, intramuscular gold.

### **Stable Therapy**

- Stable therapy does not apply to Kineret<sup>®</sup>.

### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 12 months.

### **Electronic Prior Authorization (PA)**

- Not Applicable

### **Verbal PA Requests**

- Not Applicable

## **F. Orenzia® (Abatacept)**

### **Appropriate Diagnosis**

- For prior authorization the patient must have a diagnosis of:
  - moderately to severely active rheumatoid arthritis in adults 18 years or older confirmed by a board certified rheumatologist, or
  - moderately to severely active polyarticular juvenile idiopathic arthritis in pediatric patients 6 years or older confirmed by a board certified rheumatologist.

### **Prior Treatment Trials**

- The patient must also have failed a 30-day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use. DMARDs include the following: hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, d-penicillamine, azathioprine, oral gold, intramuscular gold.

### **Stable Therapy**

- Stable therapy does not apply to Orenzia®.

### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 12 months.

### **Electronic Prior Authorization (PA)**

- Not Applicable

### **Verbal PA Requests**

- Not Applicable

## **G. Raptiva® (Efalizumab)**

### **Appropriate Diagnosis**

- For prior authorization the patient must have a diagnosis of:
  - chronic moderate to severe plaque psoriasis in adults 18 years or older confirmed by a board certified dermatologist.

### **Prior Treatment Trials**

- The patient must have had an inadequate response to phototherapy, systemic retinoids, methotrexate or cyclosporine, or failed a 6-month treatment trial with topical treatment(s), either generic, OTC, or brand, within the last year, or have a documented allergy or contraindication to all agents in this class.

### **Stable Therapy**

- Stable therapy does not apply to Raptiva®.

### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 12 months.
- Patients may be taught to self inject, under the guidance and supervision of a physician. Granting of further approvals is dependent on patient compliance.

### **Electronic Prior Authorization (PA)**

- Not Applicable

### **Verbal PA Requests**

- Not Applicable

## H. Remicade® (Infliximab)

### Appropriate Diagnosis

- For prior authorization the patient must have a diagnosis of:
  - moderately to severely active rheumatoid arthritis or active ankylosing spondylitis confirmed by a board certified rheumatologist, or
  - psoriatic arthritis confirmed by a board certified dermatologist or board certified rheumatologist, or
  - chronic severe plaque psoriasis in adults 18 years or older who are candidates for systemic therapy confirmed by a board certified dermatologist, or
  - moderately to severely active Crohn's disease in adult and pediatric patients 6 years or older confirmed by a board certified gastroenterologist, or
  - moderately to severely active ulcerative colitis in adults 18 years or older confirmed by a board certified gastroenterologist.

### Prior Treatment Trials

- For ankylosing spondylitis, the patient must also have failed a 3-month treatment trial with at least two nonsteroidal anti-inflammatory agents (NSAIDs) at maximum recommended doses, unless there is a documented adverse response or contraindication to NSAID use. Patients who have axial disease only do not require any additional treatment failures. Patients with symptoms of peripheral arthritis must also have failed a 30-day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use. DMARDs include the following: hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, d-penicillamine, azathioprine, oral gold, intramuscular gold.
- For rheumatoid arthritis or psoriatic arthritis, the patient must have also failed 30-day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use. DMARDs include the following: hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, d-penicillamine, azathioprine, oral gold, intramuscular gold.
  - The patient will need to continue on methotrexate in conjunction with Remicade® therapy, unless there is a contraindication to its use. Any contraindications or intolerance to methotrexate use will need to be identified with appropriate supportive documentation included.
- For plaque psoriasis, the patient must have had an inadequate response to phototherapy, systemic retinoids, methotrexate or cyclosporine, or failed a 6-month treatment trial with topical treatment(s), either generic, OTC, or brand, within the last year, or have a documented allergy or contraindication to all agents in this class.

- For Crohn's disease or ulcerative colitis, the patient must have had an inadequate response to one or more conventional therapies, which include aminosalicylates, corticosteroids, azathioprine/6-mercaptopurine, metronidazole, methotrexate, ciprofloxacin, or cyclosporine (ulcerative colitis only).

#### **Stable Therapy**

- Stable therapy does not apply to Remicade®.

#### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.
- For a diagnosis of ulcerative colitis, additional medical justification is required.

#### **PA Approval Timeframes**

- Approval may be given for up to 12 months.

#### **Electronic Prior Authorization (PA)**

- Not Applicable

#### **Verbal PA Requests**

- Not Applicable

## **I. Simponi® (Golimumab)**

### **Appropriate Diagnosis**

- For prior authorization the patient must have a diagnosis of:
  - moderately to severely active rheumatoid arthritis or active ankylosing spondylitis in adults 18 years or older confirmed by a board certified rheumatologist, or
  - psoriatic arthritis in adults 18 years or older confirmed by a board certified dermatologist or board certified rheumatologist.

### **Prior Treatment Trials**

- For ankylosing spondylitis, the patient must also have failed a 3-month treatment trial with at least two nonsteroidal anti-inflammatory agents (NSAIDs) at maximum recommended doses, unless there is a documented adverse response or contraindication to NSAID use. Patients who have axial disease only do not require any additional treatment failures. Patients with symptoms of peripheral arthritis must also have failed a 30-day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use. DMARDs include the following: hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, d-penicillamine, azathioprine, oral gold, intramuscular gold.
- For rheumatoid arthritis or psoriatic arthritis, the patient must have also failed 30-day treatment trial with at least one conventional disease modifying antirheumatic drug (DMARD), unless there is a documented adverse response or contraindication to DMARD use. DMARDs include the following: hydroxychloroquine, sulfasalazine, methotrexate, leflunomide, d-penicillamine, azathioprine, oral gold, intramuscular gold.
  - The patient will need to continue on methotrexate in conjunction with Simponi® therapy, unless there is a contraindication to its use. Any contraindications or intolerance to methotrexate use will need to be identified with appropriate supportive documentation included.

### **Stable Therapy**

- Stable therapy does not apply to Simponi®.

### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 12 months.

### **Electronic Prior Authorization (PA)**

- Not Applicable

### **Verbal PA Requests**

- Not Applicable

## **Growth Failure Agents in Adults**

### **Appropriate diagnosis**

- The patient must have one of the following primary diagnoses listed below confirmed by a board certified endocrinologist or a board certified gastroenterologist for short bowel syndrome.
  - Childhood onset of growth hormone deficiency
  - Adult onset of growth hormone deficiency with other deficiencies
  - Adult onset of growth hormone deficiency without other pituitary hormone deficiencies
  - Short Bowel Syndrome
- Agents include Genotropin<sup>®</sup>, Humatrope<sup>®</sup>, Norditropin<sup>®</sup>, Nutropin AQ<sup>®</sup>, Nutropin<sup>®</sup>, Saizen<sup>®</sup> and Zorbitive<sup>®</sup>.
- Adult is defined for growth hormone replacement therapy as any patient with closed epiphyses.

### **Prior Treatment Trials**

- Prior treatment trials do not apply to agents used for growth failure.

### **Stable Therapy**

- Stable therapy does not apply to agents used for growth failure.

### **Medical Justification**

- Adults being considered for treatment with growth hormone must be screened prior to initiation of therapy to verify the absence of any malignant condition. If growth failure results from an intracranial tumor, absence of tumor growth or tumor recurrence must be documented for at least 6 months before initiating growth hormone therapy.
- Patients must be tested for normal thyroid function.
- Patients will be denied if they have any of the following contraindications.
  - Pregnancy
  - Proliferative or preproliferative diabetic neuropathy
  - Pseudotumor cerebri or benign intracranial HTN
- For growth hormone deficiency, provocative testing and IGF-1 levels as well as dates must be included. For adults with childhood onset growth hormone deficiency or with additional pituitary hormone deficits, one stimulation test is required. For those with suspected growth hormone deficiency with no other pituitary hormone deficits, 2 stimulation tests are required.
- As provocative testing, Insulin Tolerance Test is **required** unless contraindicated. ITT is contraindicated in patients with seizures, CAD, abnormal EKG with history of IHD or CVD and not advised for those > age 60. If ITT is contraindicated, documentation must be provided **and** an alternative test performed. Results from



other stimulation tests (arginine, glucagon, L-Dopa, growth hormone-releasing hormone [GHRH], and combinations of these agents, excluding clonidine), may be submitted for those patients with documented contraindication to ITT.

- For patients with short bowel syndrome, the patient must be receiving specialized nutritional support such as dietary adjustments, enteral feedings, parenteral nutrition, and/or fluid and micronutrient supplement.
- The strength, daily dose, patient's height and weight must be included with all requests.
- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- For growth hormone deficiency, approval may be given for up to 6 months. For subsequent requests, the physician must submit progress reports including information regarding efficacy, adverse effect and compliance, and the results of any required lab tests. The report must include the date the patient was last seen by the physician.
- For short bowel syndrome, approval may be granted for up to 4 weeks.

### **Electronic Prior Authorization (PA)**

- Growth failure agents are not included in the electronic PA program.

### **Verbal PA Requests**

- Verbal PA requests do not apply to agents used for growth failure.

## **Growth Failure Agents in AIDS Wasting**

### **Appropriate diagnosis**

- The patient must have a diagnosis of HIV/AIDS.
- Example agents include Serostim®.

### **Prior Treatment Trials**

- Patient must be on antiretroviral therapy. The start date of the antiretroviral must be at least 120 days prior to the initiation of growth failure agent.
- Documentation of failed trial with appetite stimulants or weight gain agents (Periactin®, Marinol®, Megace®, Oxandrin®, or androgenic steroid) must be included.

### **Stable Therapy**

- Stable therapy does not apply to agents used for growth failure.

### **Medical Justification**

- Adults being considered for treatment with growth hormone must be screened prior to initiation of therapy to verify the absence of any malignant condition. If growth failure results from an intracranial tumor, absence of tumor growth or tumor recurrence must be documented for at least 6 months before initiating growth hormone therapy.
- Patients will be denied if they have any of the following contraindications.
  - Pregnancy
  - Proliferative or preproliferative diabetic neuropathy
  - Pseudotumor cerebri or benign intracranial HTN
- For approval, documentation of unintentional weight loss of 10% over 12 months, 7.5% over 6 months, or loss of muscle mass ( $BMI < 20\text{kg/m}^2$ ).
- Weight stabilization or weight gain must be reported to continue therapy.
- The duration of therapy, strength, daily dose, patient's height, weight, and BMI must be included with all requests.
- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 6 months. For subsequent requests, the physician must submit progress reports including information regarding efficacy, adverse effect and compliance, and the results of any required lab tests. The report must include the date the patient was last seen by the physician.

**Electronic Prior Authorization (PA)**

- Growth failure agents are not included in the electronic PA program.

**Verbal PA Requests**

- Verbal PA requests do not apply to agents used for growth failure.

## **Growth Failure Agents in Children**

### **Appropriate diagnosis**

- The patient must have one of the following primary diagnoses listed below.
  - Documented Growth Hormone Deficiency
  - Turner Syndrome
  - Growth Deficiency due to Chronic Renal Insufficiency (CRI)
  - Prader-Willi Syndrome
  - Severe Primary IGF-1 Deficiency (for mecasermin only)
  - Growth Hormone Gene Deletion (for mecasermin only)
- Example agents include Genotropin<sup>®</sup>, Humatrope<sup>®</sup>, Increlex<sup>®</sup>, Iplex<sup>®</sup>, Norditropin<sup>®</sup>, Nutropin<sup>®</sup>, Nutropin AQ<sup>®</sup>, Omnitrope<sup>®</sup>, Saizen<sup>®</sup>, and Tev-tropin<sup>®</sup>.
- The diagnosis must be confirmed by a board certified endocrinologist. For CRI, diagnosis may be confirmed by a board certified pediatric nephrologist.

### **Prior Treatment Trials**

- Prior treatment trials do not apply to agents used for growth failure.

### **Stable Therapy**

- Stable therapy does not apply to agents used for growth failure.

### **Medical Justification**

- Children being considered for treatment with growth hormone must be screened prior to initiation of therapy to verify the absence of any malignant condition. If growth failure results from an intracranial tumor, absence of tumor growth or tumor recurrence must be documented for at least 6 months before initiating growth hormone therapy.
- Patients will be denied if they have any of the following contraindications.
  - Pregnancy
  - Proliferative or preproliferative diabetic neuropathy (does not apply to mecasermin)
  - Pseudotumor cerebri or benign intracranial HTN (does not apply to mecasermin)
  - Closed epiphyses (after epiphyseal closure, use Adult Growth Failure Therapy criteria)
- For growth hormone (GH) deficiency, provocative testing (for children  $\geq 12$  months of age) and IGF-1 levels as well as dates must be included. Results from at least one (1) stimulation test (arginine, glucagon, L-Dopa, growth hormone-releasing hormone [GHRH], and combinations of these agents, excluding clonidine) are required. GH peak levels of  $\leq 10$  ng/ml after provocative testing support GH deficiency and justify treatment.
- Short stature in girls with Turner Syndrome is not due to GH deficiency, but growth failure due to intrinsic skeletal dysplasia. The decision to treat these

patients is not based on provocative testing but on the diagnosis of Turner Syndrome using karyotyping. For Turner Syndrome, the date and results of karyotyping must be included.

- The following diagnosis specific information is needed for approval of growth failure agents in children:
  - **Documented Growth Hormone Deficiency**
    - Diagnosis by Board Certified Endocrinologist
    - Normal thyroid function
    - Provocative testing
    - IGF-1 level
    - Height less than 5<sup>th</sup> percentile
    - Screening for intracranial malignancy and free from recurrence for at least 6 months
    - Free from following contraindications
      - Pregnancy
      - Proliferative or preproliferative diabetic neuropathy
      - Pseudotumor cerebri or benign intracranial HTN
      - Closed epiphyses (after epiphyseal closure, use Adult Growth Failure Therapy criteria)
  - **Turner Syndrome**
    - Diagnosis by Board Certified Endocrinologist
    - Normal thyroid function
    - Karyotyping with 45X (XO) date and results
    - Height less than 5<sup>th</sup> percentile
    - Screening for intracranial malignancy and free from recurrence for at least 6 months
    - Free from following contraindications
      - Pregnancy
      - Proliferative or preproliferative diabetic neuropathy
      - Pseudotumor cerebri or benign intracranial HTN
      - Closed epiphyses (after epiphyseal closure, use Adult Growth Failure Therapy criteria)
  - **Growth Deficiency due to Chronic Renal Insufficiency (CRI)**
    - Diagnosis by Board Certified Pediatric Nephrologist
    - Normal thyroid function
    - GFR and date
    - Height velocity or growth value in standard deviations below the means
    - Screening for intracranial malignancy and free from recurrence for at least 6 months
    - Free from following contraindications
      - Pregnancy
      - Proliferative or preproliferative diabetic neuropathy
      - Pseudotumor cerebri or benign intracranial HTN

- Closed epiphyses (after epiphyseal closure, use Adult Growth Failure Therapy criteria)

➤ **Prader-Willi Syndrome**

- Diagnosis by Board Certified Endocrinologist
- Normal thyroid function
- Height less than 5<sup>th</sup> percentile
- Screening for intracranial malignancy and free from recurrence for at least 6 months
- Free from following contraindications
  - Pregnancy
  - Proliferative or preproliferative diabetic neuropathy
  - Pseudotumor cerebri or benign intracranial HTN
  - Closed epiphyses (after epiphyseal closure, use Adult Growth Failure Therapy criteria)

➤ **Severe Primary IGF-1 Deficiency (for Increlex and Iplex only)**

- Diagnosis by Board Certified Endocrinologist
- Height value or growth velocity
- IGF-1 in standard deviations below the mean
- Growth hormone level
- Screening for intracranial malignancy and free from recurrence for at least 6 months
- Free from following contraindications
  - Pregnancy
  - Closed epiphyses (after epiphyseal closure, use Adult Growth Failure Therapy criteria)
- Age of at least 2 years but less than 18

➤ **Growth Hormone Gene Deletion (for Increlex and Iplex only)**

- Diagnosis by Board Certified Endocrinologist
- Screening for intracranial malignancy and free from recurrence for at least 6 months
- Free from following contraindications
  - Pregnancy
  - Closed epiphyses (after epiphyseal closure, use Adult Growth Failure Therapy criteria)
- Age of at least 2 years but less than 18

- The strength, daily dose, patient's height and weight must be included with all requests.
- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

**PA Approval Timeframes**

- Approval may be given for up to 6 months. For subsequent requests, the physician must submit progress reports including information regarding efficacy,

adverse effect and compliance, and the results of any required lab tests. The report must include the date the patient was last seen by the physician.

**Electronic Prior Authorization (PA)**

- Growth failure agents are not included in the electronic PA program.

**Verbal PA Requests**

- Verbal PA requests do not apply to agents used for growth failure.

## **H2 Antagonists**

### **Appropriate Diagnosis**

- Indicate in the clinical information section whether this request is for acute or maintenance therapy.

### **Prior Treatment Trials**

- The patient must also have failed 30-day treatment trials with two prescribed H2 Antagonists in this class, either generic, OTC or brand, within the past 6 months.
- Approval may be given without failed drug trials **if** a relevant diagnosis and documentation of testing with date and results are provided.

### **Stable Therapy**

- Stable therapy does not apply to the H2 antagonist class.

### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval timeframes are based on acute versus maintenance therapy. Approval may be given for up to 12 months for maintenance therapy.

### **Electronic Prior Authorization (PA)**

- Not Applicable

### **Verbal PA Requests**

- PA requests that meet prior usage requirement for approval may be accepted verbally.



## **Nonsteroidal Anti-inflammatory Drugs (NSAIDs)**

### **Appropriate Diagnosis**

- For COX II Inhibitors, the patient must have an appropriate diagnosis supported by documentation in the patient record, as well as any additional diagnoses and any history preventing the use of other NSAIDs.

### **Prior Treatment Trials**

- The patient must have failed 30-day treatment trials with at least 2 other therapies, either generic, OTC, or brand, within the past 6 months.

### **Stable Therapy**

- Approval may be given for children age 18 years and under who have documented stable therapy on the requested medication for 60 consecutive days or greater.

### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.
- For **Prevacid NapraPAC®** the patient must have a diagnosis of gastric ulcer, diagnosed within the past 12 months, **and** require the use of an NSAID for treatment of the signs and symptoms of rheumatoid arthritis, osteoarthritis, or ankylosing spondylitis. The patient must also have failed two 30-day treatment trials with at least two prescribed NSAIDs while on concomitant H2 or PPI therapy within the past 6 months, either generic, OTC or brand, or have a documented contraindication to all preferred agents in this class.

### **PA Approval Timeframes**

- Approval may be given for up to 12 months.

### **Electronic Prior Authorization (PA)**

- Nonsteroidal anti-inflammatory drugs (NSAIDs) are included in the electronic PA program.

### **Verbal PA Requests**

- PA requests that meet prior usage requirement for approval may be accepted verbally.

## **Phosphodiesterase Inhibitors**

### **Appropriate Diagnosis**

- Phosphodiesterase inhibitors require diagnosis of pulmonary arterial hypertension (defined by a mean pulmonary arterial pressure >25 mm Hg at rest or >30 mm Hg with exercise, by a pulmonary capillary wedge pressure  $\leq$  15 mm Hg and by peripheral vascular resistance > 3 mm Hg/L/min).
- Documentation must be provided of consultation with a specialist experienced in the treatment of pulmonary hypertension patients.
- A sole diagnosis of erectile dysfunction will not be approved.

### **Prior Treatment Trials**

- Documentation must include failure of or contraindication to at least three other available oral conventional therapies.
- Previous therapies may include oral anticoagulants, calcium channel blocking agents, digoxin, diuretics and/or oxygen supplementation.

### **Stable Therapy**

- Stable therapy does not apply to phosphodiesterase inhibitors.

### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 30 days for initial requests, with up to 3 months allowed for renewal requests.

### **Electronic Prior Authorization (PA)**

- Not Applicable

### **Verbal PA Requests**

- Not Applicable

## **Smoking Cessation**

### **Appropriate Diagnosis**

- The patient must be pregnant or within 60 days postpartum.

### **Prior Treatment Trials**

- Prior treatment trials do not apply to smoking cessation products.

### **Stable Therapy**

- Stable therapy does not apply to smoking cessation products.

### **Medical Justification**

- Medical justification includes pregnant recipients enrolled in the Quitline program in the last 30 days.

### **PA Approval Timeframes**

- Approval timeframe is dependent upon the duration of therapy for the approved medication. Only one course of therapy is allowed per pregnancy.

### **Electronic Prior Authorization (PA)**

- Not Applicable

### **Verbal PA Requests**

- Not Applicable

## **Specialized Nutritionals**

### **Appropriate Diagnosis**

- Patients who, because of illness or trauma, cannot be sustained through oral feedings and must rely on enteral nutrition therapy may qualify for coverage under Medicaid. Enteral nutrition may be administered by nasogastric, jejunostomy, or gastrostomy tubes.
- Specialized nutrition is covered for Medicaid eligible EPSDT recipients less than 21 years of age with nutritional disorders. They do not have to be tube fed, but the specialized feeding must constitute more than 50% of their nutritional needs. A qualifying diagnosis is required.
- Recipients age 21 and over who must rely on enteral feedings as their only source of nutrition may qualify for Medicaid coverage if they have a qualifying diagnosis and meet disease specific criteria.

### **Prior Treatment Trials**

- Prior treatment trials do not apply to nutritional products.

### **Stable Therapy**

- Stable therapy does not apply to nutritional products.

### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.
- Additional Information
  - Current height and weight are required.
  - Current age is required.
  - Route specialized nutritional is administered, along with the duration and number of refills is required.
- Prior authorization is for the nutritional product only and does not include any equipment or supplies necessary to administer the nutrients. Supplies and equipment used in conjunction with nutritional therapy may be covered in the Medical Supplies, Appliances and Durable Medical Equipment Program. For more information on supplies and equipment, see Chapter 14 of the Medicaid Provider Manual or contact Medicaid Provider/Recipient Services at 1-334-353-4753.

### **PA Timeframe Approval**

- Approval may be given for up to 12 months.

### **Electronic Prior Authorization (PA)**

- Not Applicable

### **Verbal PA Requests**

- Not Applicable

## **Sustained Release (SR) Oral Opioid Agonists**

### **Appropriate Diagnosis**

- Approval may be given for the treatment of intractable, chronic pain with oral SR opioid agonists (Avinza<sup>®</sup>, Embeda<sup>®</sup>, Exalgo<sup>®</sup>, Kadian<sup>®</sup>, MS Contin<sup>®</sup>, Opana ER<sup>®</sup>, Oramorph SR<sup>®</sup>, and OxyContin<sup>®</sup>). These medications are narcotic analgesics and Schedule II controlled substances and are not intended for use with acute pain, as a PRN analgesic, or for short-term pain management ( $\leq 10$  days).
- The request form must include duration of therapy, if medication is for PRN use, type of pain, and severity of pain.

### **Prior Treatment Trials**

- The patient must have failed 30-day trials with alternative pain management therapies and non-opioid adjuvant drugs to replace or enhance opioid analgesia, unless the primary diagnosis is an approved cancer diagnosis.

### **Stable Therapy**

- Approval may be given for children age 18 years and under who have been stable on the requested medication for 60 consecutive days or greater who meet the diagnosis requirements.

### **Medical Justification**

- For patients  $\geq 65$  years of age, medical justification may be provided in lieu of non-opioid adjuvant drugs.
- If the patient has a history of substance abuse or addiction, a treatment plan (a plan of action addressing continuing medical monitoring, titration, and a written signed contract for therapy) must be attached to the request, unless the patient is a nursing home resident.
- For nursing home residents with a history of substance abuse or addiction, medical justification may be submitted in lieu of a plan of action, alternate pain management choices and adjuvant therapy.

### **PA Approval Timeframes**

- Approval timeframes are diagnosis dependent and may be given for up to 12 months.

### **Electronic Prior Authorization (PA)**

- Sustained release (SR) oral opioid agonists are included in the electronic PA program.

### **Verbal PA Requests**

- Not Applicable

## **Xenical®**

### **Appropriate Diagnosis**

- To receive prior authorization for Xenical®, the patient must be 18 years of age or older and have at least one of the following primary medical diagnoses:
  - Diabetes mellitus
  - Hypertension
  - Hyperlipidemia
- For initial requests the patient's height (in inches), weight (in pounds) and BMI are required.
- Renewal requests require the patient's previous and current weights (in pounds). Continued weight loss must be documented for renewals.
- Dosage requested must not exceed 120 mg TID.

### **Prior Treatment Trials**

- There must be documentation in the patient record to support failure with prior physician supervised exercise/diet regimen(s) of at least 6 months duration. Documentation must also show that adjuvant therapy is planned.

### **Stable Therapy**

- Stable therapy does not apply to Xenical®.

### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 3 months with initial request, and up to 6 months for each subsequent request to a total approval period not to exceed 2 years for the recipient.

### **Electronic Prior Authorization (PA)**

- Not Applicable

### **Verbal PA Requests**

- Not Applicable

## **Xolair®**

### **Appropriate Diagnosis**

- Prior authorization for treatment with Xolair requires that the patient's course of treatment be recommended by a board certified pulmonologist or a board certified allergist.
- The patient must be 12 years of age or older.
- The patient must have had a positive skin or blood test reaction to a perennial aeroallergen.
- Appropriate IgE to mass ratios must be followed, with the baseline IgE levels between 30 IU/ml and 700 IU/ml.
- The patient must weigh between 30kg and 150kg.

### **Prior Treatment Trials**

- The patient must be symptomatic despite receiving a combination of either inhaled corticosteroid and leukotriene inhibitor or an inhaled corticosteroid and a long acting beta agonist or the patient must have required 3 or more bursts of oral steroids within the past 12 months.

### **Stable Therapy**

- Stable therapy does not apply to Xolair®.

### **Medical Justification**

- Medical justification may include peer-reviewed literature, medical record documentation, or other information specifically requested.

### **PA Approval Timeframes**

- Approval may be given for up to 6 months for initial request and up to 12 months for renewal requests.

### **Electronic Prior Authorization (PA)**

- Not Applicable

### **Verbal PA Requests**

- Not Applicable

**Section Six**  
**PA Form: Dispensing Pharmacy Information**

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*(Information in this area may be completed by the pharmacy).*

Below are fields to be completed on the PA Form.

<b>Form States:</b>	<b>Your Response:</b>
<b>Dispensing pharmacy</b>	Enter the pharmacy name.
<b>NPI/Provider number</b>	Enter the pharmacy NPI or provider number.
<b>Phone number with area code</b>	Enter the pharmacy phone number with area code.
<b>Fax number with area code</b>	Enter the pharmacy fax number with area code.
<b>NDC number</b>	Record the NDC number of the drug requested.